



Direct Healthcare Professional Communication

July 2023

Metamizole Sodium

("Novalgin 1 g / 2 ml Solution for Injection" and Novalgin Oblong 500 mg Film Coated Tablet) Contraindication in pregnancy and breastfeeding women.

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

Medicines containing "Metamizole Sodium" are contraindicated in pregnancy and breastfeeding women according to the decision of the Egyptian Specialized Scientific Committee for Obstetrics and Gynecology Medicines.

Further information on the safety concern and the recommendations

Based on the report issued by the EMA (EMA/143912/2019 dated 13 December 2018) stated that "Although metamizole has been on the market for nearly a century, evidence of its effects in pregnancy and breastfeeding is scarce. The review found little to suggest problems in early pregnancy, and single doses in the first 6 months might be acceptable if other analgesics cannot be used. However, there was some evidence of effects on the kidneys and circulation of the fetus if the medicine were used in the last 3 months of pregnancy, and the medicine should therefore not be used in this period. As a precaution, metamizole should not be used during breastfeeding because the infant may receive high amounts of the medicine in the milk relative to the infant's weight".

The final legally binding decision valid across the European Union was made on 20 March 2019 by the European Commission (2019) 2302 of 20 Mar 2019) considered that: Metamizole-containing medicinal products should be contraindicated in the third trimester of pregnancy due to the risks of fetal renal impairment and ductus arteriosus constriction, repeated use of metamizole during breastfeeding should be avoided. In case of a single administration of metamizole, breastmilk should be discarded for a 48-hour period before breastfeeding can be resumed.

On July 25th, 2022, following a review of medicines containing "Metamizole Sodium", Assembled Scientific Committee Specialized in Gynecological and Obstetric Diseases recommended adjusting warning on contraindication for Metamizole Sodium during pregnancy and breastfeeding (from contraindicated in 3rd trimester of pregnancy to be contraindicated in pregnancy) to the Metamizole Sodium product information.

On August 18th, 2022, Pharmacology Committee agreed with the recommendation made by the Assembled Scientific Committee Specialized in Gynecological and Obstetric Diseases.





Updated Summary of Product Characteristic (SmPC) and Package Leaflet (PIL) of Metamizole Sodium “Novalgin 1 g / 2 ml Solution for Injection” and “Novalgin Oblong 500 mg Film Coated Tablet” with the contraindication in pregnant and breastfeeding women will be available nationally following the final approval.

More about the medicine

Metamizole is a pyrazolone derivative with analgesic, antipyretic, and spasmolytic properties. “Novalgin 1 g / 2 ml Solution for Injection” and “Novalgin Oblong 500 mg Film Coated Tablet” are indicated for: -

- Acute severe pain after injury or surgery
- Colic
- Tumour pain
- Other acute or chronic severe pain, where other therapeutic measures are not indicated
- High fever not responding to other measures.

Parenteral use is indicated only where enteric administration cannot be considered. Metamizole is not to be used as routine analgesic.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Hotline: 15301

